IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#11 JCR 5/7/03

Applicants:	Barabolak et al.
Appl. No.:	10/035,320
Conf. No.:	2531
Filed:	November 8, 2001
Title:	ANTI-PLAQUE EMULSIONS AND PRODUCTS CONTAINING SAME
Art Unit:	1614
Examiner:	S. Rose
Docket No.:	112703-211

Commissioner for Patents
Washington, DC 20231

RESPONSE AFTER FINAL

Sir:

This Response is submitted in response to the Office Action dated January 10, 2003.

REMARKS

In the Office Action, Claims 1, 2, 4, 5, 15, 19, and 23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,236,699 ("*Libin I*"). Claims 3, 4, 20, 21, and 24 were further rejected under 35 U.S.C. § 103(a) as being unpatentable over *Libin I.* Claims 1-7, 9-11, 13, 15-17, and 19-21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,487,902 ("*Andersen*"). Claims 1, 2, 5-7, 9, 13-16 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,380,530 ("*Hill*"), in view of *Libin I.*

In the Office Action, Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 10 of U.S. Patent No. 6,355,265 in view of *Libin I.* Moreover, Claims 1-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 10, 12 and 29 of U.S Patent No. 6,322,806 in view of *Libin I.* Claims 1-22 are further rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 9, 12, 17, and 26 of U.S. Patent No. 6,290,985 in view of *Libin I.* Claims 1-22 were further rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 6,436,369 and 6,350,480. To overcome the

double patenting rejections, Applicants enclose herewith a terminal disclaimer. Applicants respectfully request that the terminal disclaimer be considered and the double patenting rejection be withdrawn.

In the Office Action, Claims 1, 2, 4, 5, 15, 19 and 23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by *Libin I.* Applicants respectfully request reconsideration and submit this rejection is improper for reasons set forth below.

As previously argued, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil of California,* 814 F.2d 628, 631 (Fed. Cir. 1981) (emphasis added). Moreover, "The identical invention must be shown in complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226 (Fed. Cir. 1989) (emphasis added). Yet in spite of the above, the Patent Office continues to rely on the Merck Index to support this anticipation rejection. Indeed, Applicant submits that the Patent Office's reliance on extrinsic evidence in this case is clearly improper. It is established case law that extrinsic evidence may not be used to "expand the meaning of terms and phrases used in the reference relied upon as anticipatory of the claimed subject matter." *In re Baxter Travenol Labs.*, 952 F.2d 388 (Fed. Cir. 1991)(emphasis added). Here, it is clear that the Patent Office is attempting to expand the meaning of Tween 20, which is described only as a solubilizer in *Libin*, to also include being an emulsifier using extrinsic evidence i.e., the Merck Index.

It is clear that *Libin I* fails to disclose each and every feature as required by independent Claims 1 and 15. Independent Claim 1 requires an anti-plaque emulsion that includes an emulsifier, triclosan, and a surfactant. Independent Claim 15 requires a method for reducing plaque that includes the step of orally applying to the mouth an emulsion which includes an emulsifier, triclosan, and a surfactant.

As previously argued, *Libin I* fails to disclose the emulsion features of independent Claims 1 and 15. Nowhere does *Libin I* disclose an emulsion or its use in relation to its anti-plaque mouth rinse. Applicants question how the Patent Office can rely on *Libin I* where *Libin I* discloses a solubilizer that is utilized in a sufficient amount to solubilize triclosan. *See, Libin I,* Claim 1, col. 1 at lines 53-60. In this regard, *Libin I* emphasizes solubilizing, not emulsifying triclosan. Moreover, as discussed above the Patent Office is not permitted to expand the meaning of the solubilizer disclosed in *Libin* to also mean an emulsifier. It is clear that *Libin* is

using Tween 20 only as a solubilizer not as an emulsifier. While it is perhaps arguable that Tween 20 is also useful as an emulsifier, the reference clearly does not disclose using it as one. Moreover, the Examiner is not permitted to use extrinsic evidence to characterize Tween 20 as an emulsifier when the reference is only describing it as a solubilizer. As noted above, extrinsic evidence is not allowable to "expand the meaning of terms in a reference." *See Id.*

Based on the above, the Patent Office's rejection of Claims 1, 2, 4, 5, 15 and 19 and 23 is clearly improper. Applicants submit that *Libin I* fails to anticipate these claims. Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, Claims 3, 4, 20, 21, and 24 were newly rejected under 35 U.S.C. § 103(a) as being unpatentable over *Libin I.* For the reasons argued above, Applicants assert that this rejection is improper. Again, *Libin I* does not teach or suggest the use of an emulsifier to form an anti-plaque emulsion. Applicants have found that when in emulsion form, the active ingredients are better dispersed across the dental surfaces allowing for complete oral contact with plaque covered surfaces. *Libin I* simply describes that water-insoluble triclosan requires the use of a solubilizer to form an aqueous solution. Further, *Libin I* does provide any teaching or suggestion of an anti-plaque emulsion which contains an emulsifier, triclosan, and a surfactant like that of the claimed invention.

Thus Applicants assert that the rejection of Claims 3, 4, 20, 21, and 24 under 35 U.S.C. § 103(a) is improper, and respectfully request that the rejection be withdrawn.

In the Office Action, Claims 1-7, 9-11, 13, 15-17 and 19-21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by *Andersen.* The Patent Office essentially asserts that *Andersen* discloses each and every feature of the rejected claims.

Applicants submit that the Patent Office again incorrectly relies on *Andersen* as an anticipatory reference. The Examiner's position that "they do not have to state that their surfactants are emulsifiers, if extrinsic evidence (Merck Index) establishes that such encompassed species of nonionic surfactants to be used are emulsifiers." is clearly contrary to established law. *See*, Office Action, p. 8-9. As discussed above, the Examiner is not permitted to expand the meaning of terms within a reference using extrinsic evidence.

Andersen, like *Libin I*, requires a solubilizing agent to solubilize the active agent, such as triclosan, in order to control the release of said active agent. *See, Andersen,* Claim 1, col. 10 at line 57-61. Further, *Andersen* clearly makes a distinction between the use of an emulsifier as

compared to solubilizers. Again, while it might be arguable that these solubilizers may also be emulsifiers, it is clearly not described as so in the *Anderson* reference. Moreover, extrinsic evidence is not permitted to expand the meaning of terms in a reference.

Accordingly, in view of the fact that *Andersen* fails to disclose each and every feature of the rejected claims, Applicants submit that *Andersen* fails to anticipate Claims 1-7, 9-11, 13, 15-17 and 19-21. Accordingly, Applicants respectfully request that the rejection of these claims under 35 U.S.C. § 102(b) be withdrawn.

In the Office Action, Claims 1, 2, 5-7, 9, 13-16 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hill*. The Patent Office relies on *Libin I* to remedy the deficiencies of *Hill*. Applicants submit that this rejection is improper.

As previously argued, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so, either in the references themselves or in the knowledge generally available to one ordinarily skilled in the art. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). The mere fact that the references can normally be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990).

The Patent Office admits that *Hill* fails to teach or suggest the combination of an emulsifier and a surfactant as required by the rejected claims. Further, *Libin I* cannot be used to remedy the deficiencies of *Hill*. The Patent Office incorrectly relies on *Libin I* as providing a motivation or suggestion to replace the single surfactant or single emulsifier of *Hill* with the combination thereof. Moreover, *Hill* provides no such motivation to combine *Hill* and *Libin I*.

Even if combinable, *Libin I* fails to provide such teaching or suggestion as previously discussed. Nowhere does *Libin I* discuss emulsifiers, let alone the combination of emulsifiers and surfactants. The clear emphasis of *Libin I* is to solubilize agents, such as triclosan, in order to enhance anti-bacterial activity. *See, Libin I*, col. 3, lines 53-60. Therefore, *Hill* and *Libin I*, alone or in combination, fail to teach or suggest each and every feature of the rejected claims.

Based on the fact that *Hill* and *Libin I*, alone or in combination, fail to teach or suggest every feature of the rejected claims, Applicants submit that *Hill* and *Libin I* fail to render obvious Claims 1, 2, 5-7, 9, 13-16 and 19. Accordingly, Applicants respectfully request that the rejection of Claims 1, 2, 5-7, 9 13-16 and 19 under 35 U.S.C. § 103(a) be withdrawn.

Applicants respectfully request reconsideration of their patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY _____

Robert M. Barrett
Reg. No. 30,142
P.O. Box 1135
Chicago, Illinois 60690-1135
Phone: (312) 807-4204

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